UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,486	04/07/2004	Zhi-Jian Yu	27529	7395

33357 7590 08/16/2007

ADVANCED MEDICAL OPTICS, INC.
1700 E. ST. ANDREW PLACE
SANTA ANA, CA 92705

EXAMINER	
BROWN, COURTNEY A	
ART UNIT	PAPER NUMBER
1609	
MAIL DATE	DELIVERY MODE
08/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,486	YU ET AL.	
	Examiner	Art Unit	
	Courtney A. Brown	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *14-20,44-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,21-46 and 55-57* is/are rejected.

7)☐ Claim(s) *38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/27/2004,01/10/2005and12/01/2005.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 122:

I. Claims 1- 13, 21-46, and 55-57 drawn to a multi-purpose solution, a multi-purpose solution for contact lens care, and a multi-purpose lens disinfection and cleaning solution.

II. Claims 14-16 and 47-49 drawn to a method for maintaining ocular tissue cell membrane integrity during contact lens wear.

III. Claims 17-20 and 50-54 drawn to a process for mitigating ocular tissue insult .

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process such as in claims 14-16 and 47-49 of group I which are drawn to maintaining ocular tissue cell membrane integrity during contact lens wear or the product as claimed can also be used for mitigating ocular tissue insult which is drawn in claims 17-20 and 50-54 of the present application.

Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design, mode of operation, function or effect. The examiner interprets "insult" in claims 17 and 50 to mean injury. Therefore, the process in group II is used to treat ocular tissue after injury and the process in group I is used to maintain the cell membrane of the ocular tissue while contact lens are worn. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Attorney Nicole Bradley on July 31, 2007 a provisional election was made without traverse to prosecute the invention of group I, claims 1-13,21-46, and 55-57. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-20 and 47-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objection(s)

Claim 38 is objected to because of the following informalities: It is dependent on claim 44, which is incorrect. Claims can only depend on preceding claims. Appropriate correction is required.

35 USC § 112

Specification

The use of the trademark Tetronic ® 1307, Tetronic ® 1304, Tertonic ® 1107, Tetronic ® 904, and Pluronic ® F87 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner , which might adversely affect their validity as trademarks.

Claim Rejection(s)

35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 ,26, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Trademarks are not allowed in claims. Applicant is requested to use generic chemical names in the claim.

Claim 38 is not dependent on a previous claim. Correction is required.

35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 13, 21-46, and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tusè et al. (US 6482799) in view of Zhao (US 2003/0228393), Dykens et al. (S 2003/0105167 A1), and Huth (US 2004/0120916 A1)

Applicant Claims

In reference to claims 1-7 and 22-33 of the present application, applicant claims a multipurpose solution and a multi-purpose solution for contact lens care comprising an aqueous liquid medium; cetylpyridinium chloride; a second antimicrobial component, specifically in claim 28, is selected from the group consisting of

polyhexamethylen biguanide, a polyhexamethylene biguanide salt and polyquaternium-1; a viscosity inducing component selected from the group consisting of cellulose derivatives and mixtures thereof; a buffer component selected from the group consisting of boric acid/sodium hydroxide and boric acid/sodium borate buffers; a poly(oxpropylene)-poly(oxyethylene) block copolymer surfactant selected from the group consisting of Tetronic ® 1307, Tetronic ® 1304, Tertonic ® 1107, Tetronic ® 904, and Pluronic ® F87; a chelating component; and a tonicity component.

In reference to claims 8-13 and 34-46 of the present application, applicant claims a multi-purpose solution for contact lens care comprising an aqueous liquid medium; cetylpyridinium chloride; a second antimicrobial component, specifically, in claim 36, selected from the group consisting of biguanides, biguanide polymers, monermeric, and polymeric quaternary ammonium compound, salts thereof and mixtures thereof; a viscosity inducing component selected from the group consisting of cellulose derivatives and mixtures thereof, specifically, in claim 41, is hydroxypropylmethyl cellulose; a buffer component selected from the group consisting of boric acid/sodium hydroxide and boric acid/sodium borate buffers; a poly(oxpropylene)-poly(oxyethylene) block copolymer surfactant; a chelating component, specifically, in claim 44, is EDTA; a tonicity component; and taurine.

In reference to claim 21 of the present application, applicant claims a multi-purpose contact lens disinfecting and cleaning solution comprising and aqueous liquid medium; cetylpyridinium chloride; a second microbial agent; a poly(oxpropylene)-poly(oxyethylene) block copolymer surfactant; and taurine.

In reference to claims 55-57 of the present application, applicant claims a multi-purpose solution comprising an aqueous liquid medium; a second microbial component selected from the group consisting of polyhexamethylend biguanide, a polyhexamethylene buguanide salt and polyquaternium-1.

***Determination of the Scope and Content of the Prior Art* (MPEP § 2141.01)**

In reference to claims 1-13, 21-46, and 55-57, Tusè et al. teach a novel anti-microbial system suitable for formulation in a wide variety of ophthalmic solutions. The compositions are useful for storing, cleaning, or disinfection a contact lens (see abstract). In column 22, lines 60-end, column 24, lines 50-end, Tusè et al. teach that the ophthalmic compositions of their invention are formulated and stored as aqueous solutions. Tusè et al. set forth the component of the composition , cetylpyridimium chloride, in claims 18 and 54 as a preservative . An antimicrobial preservative component of the composition of the instant application is set forth by Tusè et al. in claims teaches antimicrobial preservatives such as PHMB(polyhexamethylen biguanide) and polyhexamethylene biguanide are disclosed in column 17 , lines 35-41. The viscosity-inducing component of the composition is disclosed in column 18, lines 46-55. Tusè et al. disclose(in column 18, lines 46-55) that the ophthalmic solutions of their invention can optionally include viscosity adjusting agents, in particular, Cellulose derivatives as set forth in claims 29 and 34 of the present application. Specifically, Tusè et al. set forth hydroxypropyl methylcellulose in claim 58 which is also set forth in claim 41 of the instant application. The buffer component of the composition(boric acid/sodium borate) is disclosed in Tusè et al. Tusè et al. also set forth the poly(oxpropylene)-poly(oxyethylene) block copolymer component of the composition in claims 1,9, and 57. Specifically, Tusè et al. disclose that these block copolymers are available under tradenames such as PLURONIC in column 16, lines 25-30. These specific block copolymers are set forth in claims 3 and 26 of the present application. The chelating component of the instant application is set forth by Tusè et al. in claim 10. Specifically, in claim 11 Tusè et al set forth the use of EDTA as a chelating agent which is set forth in claim 44 of the present application. The tonicity component of the

composition in the instant application is set forth by Tusè et al. in claim 20. This component of the composition is set forth in claims8,31, and 34 of the instant application.

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

In reference to claims 13,21,and 46 of the present application, Tusè et al. does not teach the taurine component of the composition. Tusè et al. does not disclose the amounts of cetylpyridinium chloride, the cellulosic derivatives, amount of the viscosity inducing component, the poly(oxpropylene)-poly(oxyethylene) block copolymer, the second antimicrobial component, the tonicity component, or the chelating component as in claims 2, 5, 8,10,29-30 and 43. Additionally, Tusè et al. also does not disclose a specific tonicity component(a combination of sodium chloride and potassium chloride) as in done in claim 43 of the present application.

Zhao, in paragraph 185-186, teach a nutritional supplement and herb remedy for helping vision and reducing eye problem that includes taurine.

Dykens et al., on page 5 [48] teach the use of sodium chloride and potassium chloride as tonicity agents in topical(e.g., eye drops) ophthalmic solutions.

Huth teaches a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

In reference to claims 2, 5, 8, 10, 13,21, 29-30, and 43 of the present application, it would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Tusè, Zhao, Dykens and Huth to devise a multi-purpose contact lens care solution that contains all of the components disclosed by Tusè with the addition of taurine and the other noted deficiencies. Taurine is a non-essential amino acid that may impair vision when deficient in the human body. Together with zinc, taurine is required for proper eye health and vision. Also, as disclosed by Huth, on page 1, [0002], teach a contact lens care compositions comprising taurine which provide a cell membrane protection function for ocular tissue cells during contact lens wear. Thus, there is ample reason to want to include taurine in the composition of Tusè. Sodium chloride and potassium chloride are know tonicity agents. Thus, it is obvious to include well-known components in the known process. Additionally, it is routine optimization for one of ordinary skill in the art to adjust ingredients to optimize the desired results. In this case, the amounts of cetylpyridinium chloride, the viscosity inducing component, the second antimicrobial component, the tonicity component, and the chelating component are all known in the art and it is

simply a matter of routine optimization in an effort to optimize the desired results to arrive at the claimed amounts.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

MICHAEL MELLER
PRIMARY EXAMINER